REMARKS/ARGUMENTS

By the present amendment, applicants have canceled Claim 8, and amended Claims 1, 4, 7, 9, and 20. Applicants have amended independent Claims 1, 4, and 20 to specify that the compositions contain calcium silicate. Support is found in applicants' specification, as originally filed, on page 3, lines 19-23, wherein applicants state that the preferred silicate is calcium silicate. Additional support is found in applicants' Example 1 wherein Composition 1A and Composition 1B were prepared with calcium silicate. Therefore, the claims remaining for consideration by the Examiner are Claims 1-5, 7, 9, and 11-23.

The Examiner has rejected Claims 1-5, 7-9 and 11-23 under 35 U.S.C. 103(a) as being unpatentable over Corvari et al. in view of Bentolida et al.

Corvari, in paragraph [0006], states that "it has been discovered that solid dose forms of modafinil can be prepared with properties similar to that of Provigil®, without inclusion of magnesium silicate or talc". In paragraph [0004], Corvari states that U.S. Patent No. 5,618,845, (RE37,516) which is listed in the Orange Book for Provigil®, "describes modafinil preparations of a defined particle size less than about 200 microns". Corvari unexpectedly determined that modafinil compositions having properties similar to Provigil® may be prepared with a particle size less than about 200 microns, as required by Provigil®, but without magnesium silicate and talc. Thus, Corvari clearly teaches modafinil compositions having a particle size less than about 200 microns.

In direct contrast to the teachings of Corvari, applicants unexpectedly determined that modafinil compositions wherein greater than 5% to about 50% of the cumulative total of the modafinil particles in the composition have a particle size greater than about 200 microns exhibit comparable dissolution, stability, and bioavailability results as compared to Provigil®. Thus, applicants claimed particle size for modafinil is outside the range of Provigil® and the range taught by Corvari.

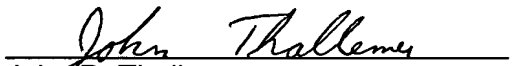
During prosecution of the Corvari patent application, Corvari, in an amendment dated July 27, 2004, on page 13, lines 10-18, stated that "Provigil® uses magnesium silicate and talc in the formulation, excipients which are hydrophobic". Corvari continues that "hydrophobic excipients can cause problems with tablet compactibility (hardness), friability, thickness, size or shape", and that "removal of the magnesium silicate and talc from the prior art formulation unexpectedly resulted in a more robust product". Thus, Corvari clearly teaches away from using a silicate in modafinil compositions.

Corvari does not place one skilled in the art in possession of applicants invention, as claimed, because the modafinil compositions taught by Corvari have a particle size less than 200 microns and do not contain calcium silicate.

With regard to Bentolila, U.S. Patent Application Publication No. 2004/0105891, applicants have submitted herewith a Rule 131 Declaration wherein applicants conceived and reduced to practice the invention claimed in the above-identified patent application in the Research and Development Department of Sandoz located in Dayton, NJ, prior to November 24, 2003, which is the U.S. filing date and 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2004/0105891 (Bentolila), as evidenced by the laboratory notebook pages 822-5-185 and 822-5-160(a), a copy of which are attached to the declaration. A copy of said declaration is attached hereto. Applicants laboratory notebook page 822-5-185 shows a pharmaceutical composition containing modafinil and calcium silicate, and references laboratory notebook page 822-5-160(a) as the lot number for the modafinil used in the composition. Laboratory notebook page 822-5-160(a) sets forth a sieve analysis worksheet for the modafinil used to prepare the modafinil composition. According to page 822-5-160(a), 21.62% of the cumulative total of modafinil particles have a particle size greater than 212 microns, which is within applicants claimed range of 5 to 50%. Thus, applicants conceived and reduced to practice one embodiment of the invention as claimed in the above-identified patent application prior to November 24, 2003, which is the U.S. filing date and 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2004/0105891.

In view of the above remarks and presentation of applicants Rule 131 Declaration, reconsideration and allowance of the pending claims are respectfully requested.

Respectfully submitted,



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